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10/661,460	09/11/2003	Robert Boock	022956-0223	7148
21125	7590	11/20/2008	EXAMINER	
NUTTER MCCLENNEN & FISH LLP			HOEKSTRA, JEFFREY GERBEN	
WORLD TRADE CENTER WEST			ART UNIT	PAPER NUMBER
155 SEAPORT BOULEVARD				3736
BOSTON, MA 02210-2604				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/661,460	Applicant(s) BOOCK ET AL.
	Examiner JEFFREY G. HOEKSTRA	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 August 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16, 18-25, 31 and 32 is/are pending in the application.
 - 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-16, 18-25, 31 and 32 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 August 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1) Certified copies of the priority documents have been received.
 - 2) Certified copies of the priority documents have been received in Application No. _____.
 - 3) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 09/12/2008 & 11/13/08
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 08/25/2008, amended claim(s) 1 and 5 is/are acknowledged. The current objections of the claim(s) is/are *withdrawn*. The following reiterated grounds of rejection are set forth:

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on 09/12/2008 and 11/13/2008 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

3. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-4, 11, 13-16, 18, 21-25, and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wulfman et al. (US 2002/0007190 A1, hereinafter Wulfman).

6. For claim 1, Wulfman discloses a tissue extraction and maceration device (Abstract), comprising:

- an outer tube (40) having a substantially open distal end (as best seen in Figures 5, 6, and 13A-13C) that is adapted to be placed on a tissue surface (as best seen in Figure 13A) (paragraphs 88-89);
- a shaft (25) rotatably disposed within the outer tube (as best seen in Figure 13C) (paragraphs 74-76) and movable between a first, proximal position in which the shaft is fully disposed within the outer tube (as best seen in Figure 13A), and a second, distal position in which a portion of a distal end of the shaft extends through the substantially open distal end of the outer tube (as best seen in Figure 13C);
- a tissue harvesting tip (90) formed on the distal end of the shaft (as best seen in Figures 8A and 8B), the tissue harvesting tip being effective to excise a tissue sample (paragraph 95-97);
- a cutting member (100) coupled to the shaft at a position proximal to the tissue harvesting tip (as best seen in Figures 8A and 8B), the cutting member being effective to macerate a tissue sample excised by the tissue harvesting tip (paragraphs 95-97); and
- a sizing screen (169) (paragraphs 109-110) disposed within the outer tube and positioned proximal to the tissue harvesting tip and the cutting member (as best seen in Figure 12).

7. For claim 2, Wulfman discloses the tissue extraction and maceration device, further comprising: a biasing element (20) (paragraphs 72-73) effective to bias the shaft to the proximal position (as best seen in Figures 1 and 13A-13C).
8. For claim 3, Wulfman discloses the tissue extraction and maceration device, further comprising: a trigger mechanism (12) connected to the shaft, wherein, upon actuation, the trigger mechanism is effective to overcome the biasing force to move the shaft from the proximal position to the distal position (paragraph 72).
9. For claim 4, Wulfman discloses the tissue extraction and maceration device, wherein the open distal end of the outer tube is adapted to form a seal with a tissue surface (paragraphs 88-89).
10. For claim 10, Wulfman discloses the tissue extraction and maceration device, wherein the cutting member comprises at least one blade member (102) extending radially from the shaft (paragraph 97) (as best seen in Figures 8A and 8B).
11. For claim 11, Wulfman discloses the tissue extraction and maceration device, wherein each blade member has a curved shape (paragraph 97) (as best seen in Figures 8A and 8B).
12. For claim 13, Wulfman discloses the tissue extraction and maceration device, wherein the harvesting tip comprises a substantially semi-cylindrical housing (90) having a cutting surface (94) formed around a periphery thereof (paragraph 95-96) (as best seen in Figures 8A and 8B).
13. For claims 14-16, Wulfman discloses the tissue extraction and maceration device, wherein the harvesting tip is adapted to penetrate tissue to remove a

predetermined volume of tissue when moved from the proximal position to the distal position (paragraph 18) and when the harvesting tip is moved from the proximal position to the distal position the predetermined volume of tissue per tissue sample collected is capable of being about 0.9 cm³.

14. For claim 18, Wulfman discloses the tissue extraction and maceration device, wherein the sizing screen includes openings (171) formed therein (as best seen in Figure 12), wherein the openings are defined by a wall (169) having an upstream edge (as best seen in Figure 12) that is capable of cutting tissue having a size greater than the circumference of the openings (paragraphs 109-112).

15. For claim 21, Wulfman discloses the tissue extraction and maceration device further comprising a driver mechanism (24) (paragraph 74-76) coupled to the shaft (as best seen in Figure 1) and effective to rotate the shaft at a speed in the range of about 100 to 5000 rpm (paragraph 75).

16. For claim 22, Wulfman discloses the tissue extraction and maceration device, wherein the harvesting tip of the shaft is adapted to extend beyond the outer tube by a predetermined distance (as best seen in Figure 13C).

17. For claim 23, Wulfman discloses the tissue extraction and maceration device, wherein the predetermined distance is capable of being in the range of about 1 mm to 5 mm (as best seen in Figure 13C).

18. For claim 24, Wulfman discloses the tissue extraction and maceration device, wherein the predetermined distance is capable of being about 3 mm (as best seen in Figure 13C).

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19. For claim 25, Wulfman discloses the tissue extraction and maceration device, wherein the outer tube is coupled to a vacuum pump (18) that is effective to draw tissue through at least a portion of the outer tube (paragraphs 73 and 83).

20. For claim 31, Wulfman discloses a tissue harvesting device (Abstract), comprising:

- a handle housing (12) having a trigger coupled thereto (paragraphs 67, 71, and 72);
- an outer tube (120) extending from the handle housing and rotatable relative to the handle housing (paragraph 100) (as best seen in Figure 9A);
- a shaft (25) rotatably disposed within the outer tube and movable between a first, proximal position in which the shaft is fully disposed within the outer tube (as best seen in Figure 13A), and a second, distal position in which a portion of a distal end of the shaft extends through a substantially open distal end of the outer tube (as best seen in Figure 13C);
- a tissue harvesting tip (113) formed on the distal end of the shaft (as best seen in Figure 9A), the tissue harvesting tip being effective to excise a tissue sample (paragraphs 95-98); and
- a cutting member (115) coupled to the shaft at a position proximal to the tissue harvesting tip (as best seen in Figure 9A), the cutting member being effective to macerate a tissue sample excised by the tissue harvesting tip (paragraphs 95- 98).

21. For claim 32, Wulfman discloses a tissue harvesting device, comprising:

- a substantially hollow cylindrical member (252') (as best seen in Figure 24) (paragraphs 140-142) having a substantially flattened distal end (as best seen in Figures 23 and 24) and a plurality of cutting teeth (254') formed around an outer sidewall thereof (as best seen in Figure 24) and having openings (482) formed therein and extending into an inner lumen (236') of the cylindrical member (paragraph 140), the plurality of cutting teeth protruding from the outer sidewall such that the plurality of cutting teeth are effective to excise a plurality of tissue samples upon axial rotation of the cylindrical member and to deliver the plurality of tissue samples to the inner lumen (paragraphs 140-142).

Claim Rejections - 35 USC § 103

22. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

23. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman in view of Wiley (US 5,489,291). Wulfman discloses the tissue extraction, maceration, and harvesting device, as set forth above, except for expressly disclosing the substantially open distal end of the outer tube is defined by an edge wall at an angle that is angled with respect to a longitudinal axis of the outer tube, wherein the angle is in the range of about 30° to 75° and about 40°, and wherein the edge wall includes surface features comprising ridges formed thereon. Wiley discloses a tissue extraction, maceration and harvesting device (26), comprising *inter alia*: an outer tube (34) (as best

seen in Figure 3) having a substantially open distal end (as best seen in Figure 3) defining an edge wall (38) at an angle (as best seen in Figure 3) that is angled with respect to a longitudinal axis of the outer tube (as best seen in Figure 3), wherein the angle is in the range of about 30° to 75° and about 40° (as best seen in Figure 3), and wherein the edge wall includes surface features comprising ridges formed thereon (column 4 line 59 - column 5 line 2). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Wulfman and Wiley. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the tissue extraction, maceration, and harvesting device as taught by Wulfman with the tissue extraction, maceration, and harvesting device as taught by Wiley to achieve the predictable results of severing tissue.

24. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wulfman. Wulfman discloses the tissue extraction, maceration, and harvesting device, as set forth above, except for expressly disclosing the sizing screen having a diameter of about 1 mm. However, Wulfman teaches configuring the size of the aspiration ports with a "sufficient cross-section to remove desired volumes of fluids and particulates"

(paragraph 104), thus teaching a tissue extraction, maceration, and harvesting device including a sizing screen having a diameter in the range of about 0.7 mm to 1.3 mm.

25. Thus, Wulfman discloses the claimed invention but does not disclose expressly the sizing screen having a diameter of about 1 mm. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the tissue extraction, maceration, and harvesting device as taught by Wulfman with the sizing screen having a diameter of about 1 mm, because Applicant has not disclosed that sizing screen having a diameter of about 1 mm provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with aspiration ports with a "sufficient cross-section to remove desired volumes of fluids and particulates" (paragraph 104) as taught by Wulfman, because it provides appropriately sized ports or sizes screens and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Wulfman. Therefore, it would have been an obvious matter of design choice to modify Wulfman to obtain the invention as specified in the claim(s).

Response to Arguments

26. Applicant's arguments filed 08/25/2008 have been fully considered but they are not persuasive. Applicant argues the rejection of the claims as set forth and reiterated above, specifically arguing for independent claim 1, 31, and 32, Wulfman does not disclose, teach, and/or fairly suggest:

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- (a) "the cutting member being effective to macerate a tissue sample excised by the tissue harvesting tip", wherein the cited cutting member is not capable of macerating a tissue sample excised by the tissue harvesting tip;
- (b) "a sizing screen ... positioned proximal the tissue harvesting tip and the cutting member", wherein the sizing screen is "not meant to retrain particulate, as would be the general function of a sizing screen", wherein the cited sizing screen does "nothing to reduce the size of the tissue so it can eventually pass";
- (c) "a plurality of cutting teeth having openings formed therein", wherein "the cutting members [cited as the plurality of cutting teeth] do not have openings formed therein... and instead are solid portions extending from the body of the attachment element. The ports... are actually formed in the body of the attachment element and not in the cutting members"; and
- (d) "the plurality of cutting teeth are effective to excise a plurality of tissue samples... to deliver the plurality of tissue samples to the inner lumen".

27. The Examiner disagrees, maintains the rejection as cited and reiterated above, and in response notes the following:

28. In response to applicant's argument that (a) that Wulfman does not disclose, teach, and/or fairly suggest "the cutting member being effective to macerate a tissue sample excised by the tissue harvesting tip", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior

art. If the prior art structure is capable of performing the intended use, then it meets the claim.

29. In this case, Wulfman discloses a cutting member capable of macerating a tissue sample excised by the tissue harvesting tip. Wulfman discloses and shows two cutting surfaces, cited as the "tissue harvesting tip" and the "cutting member above, that both rotate to cut, excise, and/or macerate tissue (paragraphs 95-97). Wulfman discloses and shows the distally disposed tissue harvesting tip (90) (as best seen in Figure 8A) is first advanced into a bodily lumen for tissue cutting and removal and the proximally disposed cutting member is secondarily advanced into the bodily lumen for tissue cutting and removal. Upon introduction to the bodily lumen, the tissue harvesting tip when rotated will cut or excise a tissue sample from the lumen and following advancement of the device through the lumen, the excised tissue is capable of cutting and/or macerating the excised tissue.

30. It appears Applicant is relying heavily upon the functional limitations "excise" and "macerate. Absent any special definition in the instant Specification upon which Applicant does not appear to be relying, the terms "excise" and "macerate" are being given their broadest reasonable interpretation under their "plain meaning", which may be generally defined as "to cut off" and "to separate into parts", respectively. Wulfman disclose and shows a "tissue harvesting tip" that cuts off a tissue sample and a "cutting member" that is capable of separating the cut off tissue sample into parts.

31. The Examiner reiterates, as set forth and cited above, that the functional limitations appearing to define the structure and/or cooperative structural relationship(s)

of and/or between the "tissue harvesting tip" and the "cutting member" do not positively recite and/or result in structural differences that patentably distinguish over Wulfman.

32. In response to applicant's argument (b) that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the sizing screen is "not meant to retrain particulate, as would be the general function of a sizing screen" and/or the sizing screen does "nothing to reduce the size of the tissue so it can eventually pass") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

33. In response to applicant's argument (b) that Wulfman does not disclose, teach, and/or fairly suggest "a sizing screen ... positioned proximal the tissue harvesting tip and the cutting member", the Examiner notes, as set forth and cited above, Wulfman discloses and shows a sizing screen (169) disposed proximate the tissue harvesting tip and the cutting member. As broadly as structurally claimed and absent any special definition in the instant Specification upon which Applicant does not appear to be relying, the term the "sizing screen" is being given its broadest reasonable interpretation under the "plain meaning", which may be generally defined as "a mesh-like device for separating or sorting smaller particles or objects from larger ones". Wulfman discloses and shows a mesh-like device (169) capable of separating or sorting smaller tissue samples from larger ones. Moreover with respect to Applicant's assertion that the

embodiments of Figure 12 and that of Figure 8A could not be combined, the Examiner disagrees and notes Wulfman discloses Figure 8A is "a cutter assembly" and Figure 12 is "a cutter assembly incorporating a stationary bearing".

34. In response to Applicant's argument (c) that Wulfman does not disclose, teach, and/or fairly suggest "a plurality of cutting teeth having openings formed therein", wherein "the cutting members [cited as the plurality of cutting teeth] do not have openings formed therein... and instead are solid portions extending from the body of the attachment element. The ports... are actually formed in the body of the attachment element and not in the cutting members", the Examiner notes Wulfman discloses the cutting members (254') may be "preferably machined as an integral piece" (paragraph 140) with central block 252' having openings (482) therein.

35. In response to Applicant's argument (d) that Wulfman does not disclose, teach, and/or fairly suggest "the plurality of cutting teeth are effective to excise a plurality of tissue samples... to deliver the plurality of tissue samples to the inner lumen", the Examiner notes Wulfman discloses that the cutting member (254') are provided for intraluminal tissue removal (i.e. cutting, excising, and/or maceration) and the openings (482) therein are for aspiration of removed tissue through the inner lumen (236') (paragraph 140).

Conclusion

36. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736